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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,078	08/23/2000	Annette Bistrup	06510-107CIP2	2678

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EXAMINER	
MORAN, MARJORIE A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/645,078	BISTRUP ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *4-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1,4* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *6* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to a protein, classified in class 530, subclass 350.

II. Claim4-7, drawn to a nucleic acid, expression cassette and cell comprising the nucleic acid, classified in class 536, subclass 23.2.

III. Claim 8, drawn to a method of expressing a protein, classified in class 435, subclass 69.1.

IV. Claim 9, drawn to a monoclonal antibody, classified in class 530, subclass 388.1.

V. Claim 10, drawn to a method of inhibiting a binding event, classified in class 435, subclass 7.1.

VI. Claims 11-12, drawn to a method of modulating/inhibiting selectin binding in a mammalian host, classified in class 514, subclass 2.

VII. Claim 13, drawn to a method of diagnosing a disease state, classified in class 435, subclass 7.1.

VIII. Claim 14, drawn to a method of determining whether an agent inhibits sulfotransferase, classified in class 435, subclass 15.

IX. Claim 15, drawn to a nonhuman transgenic animal, classified in class 800, subclass 13.

The inventions are distinct, each from the other because of the following reasons:

Groups I, V-VIII are separate and distinct from Group II because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups I and V-VIII, the critical feature is a polypeptide whereas for Group II the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of Group I to be directed as to its synthesis by a polynucleotide of Group II, however, the

completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Group I may be made synthetically.

Each of Inventions I and V-VIII is separate and distinct from Invention IV as the polypeptides of Inventions I and V-VIII are structurally and biochemically different than the antibody of Invention IV. While the antibody of Group IV may bind to the polypeptide of Group I, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner. Inventions I and V-VIII are therefore separate and distinct from Invention IV.

None of Inventions I and III-VIII is related to Invention IX. The animal of Group IX is not limited to comprise the polypeptide or antibody of Groups I or IV, and is not one made by any of the methods of Groups III and V-VIII, therefore the Groups are not related.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cell of Group II can be used in cellular inhibition studies, to produce other proteins, to produce cell growth factors, etc.

Invention II is separate and distinct from Group IV, as Invention II is drawn to polynucleotides, while the claim of Group IV is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention IV would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Invention III is separate and distinct form each of Inventions V-VIII. Although the methods of Groups V-VIII may use the product produced in the method of Group III, they are not limited to do so, and may use a product made or isolated by a different method; e.g. a polypeptide produced synthetically, or purified from tissue. Further, the methods of Groups V-VII are directed to a different result and recite different method steps then does the method of Group III. For these reasons, Group III is separate and distinct from each of Groups V-VIII.

Inventions V-VIII are separate and distinct. Although the Groups are related in that each recites use of the same polypeptide, the method(s) of each Group are directed to different results, recite use of different products (other than the polypeptide), and recite different method steps. In addition, the methods of each Groups may be performed without knowledge of or reference to the steps or results of the method of any other Group. For these reasons, each of Groups V-VIII is separate and distinct.

Invention I is related to Inventions V-VIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used in any of the methods of Groups V-VIII.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, therefore restriction for examination purposes as indicated is proper. Further, because these inventions are distinct for the reasons given above and the search required for Groups I and IV-IX is not required for Group II, the search required for Group II is not required for Groups I and IV-VIII, the search required for Group IV is not required for Groups I-III and V-IX, and the search required for Group IX is not required for Groups I-VIII, restriction for examination purposes as indicated is proper.

During a telephone conversation with Paula Borden on 7/5/02 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-3. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

An action on the merits of elected claims 1-3 follows.

Information Disclosure Statement

The information disclosure statements (IDS) filed on 2/6/01 and 10/17/02 have been considered in full.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by SPIRO et al. (IDS ref: Biochem. J. (10/1/1996) vol. 319 (1), pp. 209-216).

SPIRO teaches a GlcNAc-6-sulfotransferase expressed in rats (p. 209), thereby anticipating claims 1 and 3. It is noted that the specification defines HEC-GLCNAC6ST on page 4 as a mammalian glycosyl sulfotransferase. The enzyme taught by SPIRO is a mammalian glycosyl sulfotransferase, therefore claims 1 and 3 are anticipated.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by BIERHUIZEN et al. (IDS ref: PNAS (10/1992), vol. 89, pp. 9326-9330).

BIERHUIZEN teaches a βGlcNac sulfotransferase isolated from humans (pp. 9328-9329), thereby anticipating claims 1-3.

Conclusion

Claims 1-3 are rejected; claims 4-15 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

mam
March 10, 2003